

STATE OF MISSOURI  
MISSOURI BOARD OF PHARMACY

IN RE:	)	
	)	
HEART OF AMERICA PHARMACY, LLC	)	
4338 E. 142 <sup>nd</sup> Street	)	Complaint No. 2016-005583
Grandview, MO 64030	)	
Permit No. 2016013149	)	

**SETTLEMENT AGREEMENT BETWEEN MISSOURI  
BOARD OF PHARMACY AND HEART OF AMERICA PHARMACY, LLC**

Come Now Heart of America Pharmacy, LLC ("Respondent" or "Heart of America") and the Missouri Board of Pharmacy ("Board" or "Petitioner") and enter into this Settlement Agreement for the purpose of resolving the question of whether Respondent's permit to operate a pharmacy will be subject to discipline.

Pursuant to the terms of Section 536.060, RSMo, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri and, additionally, the right to a disciplinary hearing before the Board under Section 621.110, RSMo, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Respondent acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing of the charges against it; the right to appear and be represented by counsel; the right to have all charges against it proved upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against it; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against it and, subsequently, the right to a disciplinary hearing before the Board at which time it may present evidence in mitigation of discipline; and the right to recover attorney's fees incurred in defending this action against its permit. Being aware of these rights provided it by operation of law, Respondent knowingly and

voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document, as they pertain to it.

Respondent acknowledges that it has received a copy of the draft complaint to be filed with the Administrative Hearing Commission, the investigative report, and other documents relied upon by the Board in determining there was cause for discipline against Respondent's permit.

For the purpose of settling this dispute, Respondent stipulates that the factual allegations contained in this Settlement Agreement are true and stipulates with the Board that Respondent's permit to operate a pharmacy, numbered 2016013149, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo

#### **JOINT STIPULATION OF FACTS**

1. The Board is an agency of the State of Missouri created and established pursuant to Section 338.110, RSMo<sup>1</sup>, for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.

2. Heart of America Pharmacy, LLC, 4338 E. 142 St., Grandview, MO 64030 ("Heart of America"), is permitted by the Board under permit number 2016013149.

3. Heart of America's permit became current and active on April 26, 2016.

4. Midwestern Holdings, LLC d/b/a Heartland Medical, LLC ("Heartland Medical"), 7955 Flint Street, Lenexa, Kansas, is permitted by the Board under permit number 2015008181. Heartland Medical's permit was at all times relevant herein current and active.

5. Heartland Medical is a pharmacy.

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<sup>1</sup> All statutory references are to the Revised Statutes of Missouri (2016), as amended, unless otherwise stated.

6. On or about September 7, 2016, the Board received email correspondence from pharmacist J.R. alleging that a pharmacy technician at Heart of America had been processing refills and receiving faxes for new orders for Heartland Medical without a pharmacist present.

7. Inspector Wolzak investigated the allegations and visited both Heartland Medical and Heart of America on September 21, 2016, as part of her investigation.

8. As of September 21, 2016, Heart of America had only two employees: pharmacy technician W.K. and pharmacist-in-charge ("PIC") D.K.

9. Pharmacy technician W.K. became employed as a full-time pharmacy technician with Heartland Medical in November, 2015.

10. On April 5, 2016, pharmacy technician W.K. began working full-time at Heart of America.

11. Pharmacy technician W.K. told Inspector Wolzak that most of the time he was at Heart of America by himself with no pharmacist present.

12. Pharmacist D.K. officially started employment as the pharmacist-in-charge ("PIC") of Heart of America on June 27, 2016, but was not physically present at Heart of America Pharmacy until August 1, 2016. Like pharmacy technician W.K., PIC D.K. began his employment at Heartland Medical's location.

13. Pharmacist J.R. started employment with Heartland Medical in February, 2016.

14. Pharmacist J.R. worked as the PIC of Heart of America from the date the pharmacy received its license until D.K. assumed the role June 27, 2016, and then J.R. remained and always was a staff pharmacist at Heartland Medical until her employment ended.

15. On September 21, 2016, pharmacy technician W.K. explained to and showed — Inspector Wolzak his daily employment duties at Heart of America while she observed.

16. Pharmacy technician W.K.'s work duties at Heart of America included prescription orders for Heartland Medical, including new prescriptions faxed to Heartland Medical and auto-order refills.

17. Pharmacy technician W.K. processed Heartland Medical's new prescription orders while working at Heart of America as follows:

A. He accessed Heartland Medical's database to select and review the orders and "adjudicate" them for submission to insurance, which means verifying the information on the order matched the prescription image generated on the computer.

B. Once submitted to insurance, he generated prescription labels on the computer and placed the labels in a network drive for employees at Heartland Medical to access, print and attach to the drug products it mailed out to patients.

18. Pharmacy technician W.K.'s work duties at Heart of America also included accessing Heartland Medical's database to determine whether Heartland Medical's patients were due for refills, the process for which was as follows:

A. He accessed Heartland Medical's "pending order queue" which contained prescriptions due for 90-day auto-order refills.

B. He then reviewed comments left by Heartland Medical's customer services representative who had previously contacted the patient to determine whether the refill was needed.

C. If the patient said no refill was necessary, W.K. would change the refill date to 30 days later or a date specifically indicated by the patient.

D. If a refill was necessary, W.K. processed the refill as described above for new-prescription orders.

19. Pharmacy technician W.K. also was part of a group e-mail alert system involving Heartland Medical patients who needed supplies before their prescription was due for the 90-day auto-order refill or for some other circumstance needing quick review. W.K. reviewed and made the decision on outcomes for these email alerts at Heart of America daily until 12:00 pm.

20. Pharmacy technician W.K. also handled returns for Heartland Medical based on wrong patient addresses or refusal of delivery while working at Heart of America, as follows:

A. He accessed the “returns queue” in the Heartland Medical database and called the patient to see if there was an updated address.

B. If the patient did not answer, he updated the system, reversed the order and put the order on hold.

C. If the patient gave a new address, the product would be re-shipped to new address.

D. If the patient refused, he reversed the order and put it on hold until the patient was ready to receive more product.

21. Pharmacy technician W.K. estimated that he assisted Heartland Medical with 50 prescriptions per day while working at Heart of America.

22. On September 21, 2016, while working at Heart of America, pharmacy technician W.K. initiated the filling process for 29 prescriptions to be labeled and shipped from Heartland Medical for 11 patients. The name of the pharmacist on these 29 prescriptions is PIC J.H.

23. Pharmacist J.R. verifies approximately 150 prescriptions per day at Heartland Medical, half of which are processed at Heart of America.

24. Records show that between April 5, 2016, and April 25, 2016, while Heart of America was an unlicensed pharmacy, pharmacy technician W.K. submitted and initiated the filling of prescriptions for Heartland Medical while working at Heart of America.

25. Records show that between June 1, 2016, and July 31, 2016, pharmacy technician W.K. submitted and initiated the filling of prescriptions for Heartland Medical while working at Heart of America without a pharmacist physically present and supervising.

26. General Manager/Pharmacy Manager/Pharmacy Technician F.L. also told Inspector Wolzak that “moving forward,” pharmacy technician W.K. would be working only at Heartland Medical until insurance contracts and claims were ready at Heart of America.

27. Neither Heart of America nor Heartland Medical held a Class-J permit during the aforementioned time periods. Heart of America received a Class J Permit on June 28, 2017 and Heartland Medical received a Class J permit on July 24, 2017.

28. On March 22, 2017, the Board made demand on Heart of America to cease and desist Class-J Shared Service activities with Heartland Medical in the State of Missouri without a Class-J pharmacy permit.

29. By correspondence dated April 4, 2017, Heart of America advised the Board that it had “terminated the processes” described in the Board’s March 22, 2017 cease and desist letter.

30. Missouri law states:

(6) A pharmacy permit shall be required for performing non-dispensing activities if the pharmacist is using a pharmacy technician to assist in the practice of pharmacy at the location where non-dispensing activities are being performed, provided that a pharmacy permit shall not be required for sites used solely by the pharmacist for administering vaccines as authorized by Chapter 338, RSMo, and the rules of the board. Pharmacy technicians shall only be authorized to work under the direct supervision of a pharmacist as provided by section 338.013, RSMo, and 20 CSR 2220-2.700.

20 CSR § 2220-6.055(6).

31. Missouri statute defines “pharmacy” as:

1. Pharmacy refers to any location where the practice of pharmacy occurs or such activities are offered or provided by a pharmacist or another acting under the supervision and authority of a pharmacist, including every premises or other place:

- (1) Where the practice of pharmacy is offered or conducted;
- (2) Where drugs, chemicals, medicines, any legend drugs under 21 U.S.C. Section 353, prescriptions, or poisons are compounded, prepared, dispensed or sold or offered for sale at retail;
- (3) Where the words “**pharmacist**”, “**apothecary**”, “**drugstore**”, “**drugs**”, and any other symbols, words or phrases of similar meaning or understanding are used in any form to advertise retail products or services;
- (4) Where patient records or other information is maintained for the purpose of engaging or offering to engage in the practice of pharmacy or to comply with any relevant laws regulating the acquisition, possession, handling, transfer, sale or destruction of drugs, chemicals, medicines, prescriptions or poisons.

§ 338.210.1, RSMo.

32. Missouri law defines the practice of pharmacy as:

1. The “**practice of pharmacy**” means the interpretation, implementation, and evaluation of medical prescription orders, including any legend drugs under 21 U.S.C. Section 353; receipt, transmission, or handling of such orders or facilitating the dispensing of such orders; the designing, initiating, implementing, and monitoring of a medication therapeutic plan as defined by the prescription order so long as the prescription order is specific to each patient for care by a pharmacist; the compounding, dispensing, labeling, and administration of drugs and devices pursuant to medical prescription orders and administration of viral influenza, pneumonia, shingles, hepatitis A, hepatitis B, diphtheria, tetanus, pertussis, and meningitis vaccines by written protocol authorized by a physician for persons twelve years of age or older as authorized by rule or the administration of pneumonia, shingles, hepatitis A, hepatitis B, diphtheria, tetanus, pertussis, and meningitis vaccines by written protocol authorized by a physician for a specific patient as authorized by rule; the participation in drug selection according to state law and participation in drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records thereof; consultation with patients and other health care practitioners, and veterinarians and their clients about legend drugs, about the safe and effective use of drugs and devices; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management and control of a pharmacy. No person shall engage in the practice of pharmacy unless he is licensed under the provisions of this

chapter. This chapter shall not be construed to prohibit the use of auxiliary personnel under the direct supervision of a pharmacist from assisting the pharmacist in any of his or her duties.

§ 338.010.1, RSMo.

33. Respondent violated 20 CSR § 2220-6.055(6), § 338.010.1, RSMo, and § 338.210.1, RSMo by authorizing a pharmacy technician to assist in the filling, entering, reviewing, processing, adjudicating, and/or verifying of prescriptions and orders at Respondent's location prior to obtaining a Missouri pharmacy permit.

34. Missouri law also states:

(1) In lieu of a non-electronic (manual) record-keeping system, a pharmacy may elect to maintain an electronic data processing (EDP) record keeping-system. All information concerning the compounding, dispensing, or selling by a pharmacy of any drug, device, or poison pursuant to a lawful prescription which is entered into an EDP system at any pharmacy shall be entered only by a licensed pharmacist or by a technician or intern pharmacist under the direct supervision and review of a licensed pharmacist. Prior to dispensing, a pharmacist shall personally verify the accuracy of prescription data entered into the EDP for each original prescription. The EDP system shall comply with all applicable state and federal controlled substance laws and regulations.

20 CSR § 2220-2.080(1).

35. Missouri law further provides:

(1) A pharmacy technician is defined as any person who assumes a supportive role under the direct supervision and responsibility of a pharmacist and who is utilized according to written standards of the employer or the pharmacist-in-charge to perform routine functions that do not require the use of professional judgement in connection with the receiving, preparing, compounding, distribution, or dispensing of medications.

20 CSR § 2220-2.700(1).

36. By allowing a pharmacy technician at Respondent's location who was not under the direct supervision of a pharmacist to assist in the filling, entering, reviewing, processing, adjudicating, and/or verifying of prescriptions and orders to be dispensed by Heartland Medical,



Respondent violated 20 CSR § 2220-6.055(6), 20 CSR § 2220-2.080(1) and 20 CSR § 2220-2.700(1).

37. A Class J Shared Service pharmacy permit is defined in 20 CSR § 2220-2.020(9) as follows:

(J) Class J: Shared Service. A pharmacy engaged in the processing of a request from another pharmacy to fill or refill a prescription drug order, or that performs or assists in the performance of functions associated with the dispensing process, drug utilization review (DUR), claims adjudication, refill authorizations, and therapeutic interventions;

38. Missouri law defines the circumstances under which a pharmacy may share services with another pharmacy, which include each pharmacy location obtaining a Class J permit, to-wit:

(1) Class J: Shared Services: Shared Service Pharmacy is defined as the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order, or that performs or assists in the performance of functions associated with the dispensing process, drug utilization review (DUR), claims adjudication, refill authorizations, and therapeutic interventions.

(A) A pharmacy may perform or outsource centralized prescription processing services provided the parties:

1. Have the same owner, or have a written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of said contract in compliance with federal and state laws and regulations;
2. Maintain separate licenses for each location involved in providing shared services; and
3. Share a common electronic file to allow access to sufficient information necessary or required to fill or refill a prescription drug order. 20 CSR § 2220-2.650(1)(A).

39. Respondent violated 20 CSR § 2220-2.650(1)(A) by failing to obtain a Class J permit and by sharing services with another pharmacy that also did not have a Class J permit.

40. By operating as a Class J pharmacy without a valid Class J pharmacy permit,

Respondent also violated 20 CSR § 2220-2.020(10), which states:

(10) Pharmacy applications for initial licensure or renewals of a license shall accurately note each class of pharmacy that is practiced at the location noted on the application or renewal thereof. The permit (license) issued by the board shall list each class of licensure that the pharmacy is approved to engage in. Whenever a change in service classification occurs at a pharmacy the permit must be sent to the board with a notarized statement explaining any additions or deletions of pharmacy classes that are to be made.

41. By operating as a Class J pharmacy without a valid Class J pharmacy permit,

Respondent also violated § 338.220.1(10), RSMo, which prohibits the opening, establishment, operation, or maintenance of a pharmacy without first obtaining a proper permit from the Board, to-wit:

1. It shall be unlawful for any person, copartnership, association, corporation or any other business entity to open, establish, operate, or maintain any pharmacy as defined by statute without first obtaining a permit or license to do so from the Missouri board of pharmacy. The following classes of pharmacy permits or licenses are hereby established:

\* \* \*

(10) Class J: Shared service.

### **JOINT CONCLUSIONS OF LAW**

42. Cause exists for Petitioner to take disciplinary action against Respondent's permit to practice pharmacy for its violation of §338.210.5, RSMo, which provides:

5. If a violation of this chapter or other relevant law occurs in connection with or adjunct to the preparation or dispensing of a prescription or drug order, any permit holder or pharmacist-in-charge at any facility participating in the preparation, dispensing, or distribution of a prescription or drug order may be deemed liable for such violation.

43. Cause exists for Petitioner to take disciplinary action against Respondent's permit to operate as a pharmacy under 20 CSR § 2220-2.010(1)(O), which provides:

(0) When a pharmacy permit holder knows or should have known, within the usual and customary standards of conduct governing the operation of a pharmacy as defined in Chapter 338, RSMo, that an employee, licensed or unlicensed, has violated the pharmacy laws or rules, the permit holder shall be subject to discipline under Chapter 338, RSMo.

44. Cause exists for Petitioner to take disciplinary action against Respondent's pharmacy permit under §338.055.2(5), (6), (10), (12), and (13), RSMo, which states, in pertinent parts:

2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

\* \* \*

(5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;

(6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

\* \* \*

(10) Assisting or enabling any person to practice or offer to practice any profession licensed or regulated by this chapter who is not registered and currently eligible to practice under this chapter.

\* \* \*

(12) Failure to display a valid certificate or license if so required by this chapter or any rule promulgated hereunder;

\* \* \*

(13) Violation of any professional trust or confidence;

### **JOINT AGREED DISCIPLINARY ORDER**

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of Section 621.045.3, RSMo:

A. Respondent's permit numbered 2016013149 shall be placed on **PROBATION** for a period of **THREE (3) YEARS** ("disciplinary period"). The period of probation shall constitute the disciplinary period. The terms of discipline shall be as follows:

**The following terms apply for the entire disciplinary period.**

1. Respondent shall pay all required fees for licensing to the Board and shall renew its pharmacy license prior to October 31 of each licensing year.
2. Respondent shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.
3. If requested, Respondent shall provide the Board a list of all licensed pharmacists employed by the Respondent, and the individuals' current home addresses and telephone numbers.
4. If, after disciplinary sanctions have been imposed, Respondent fails to keep its pharmacy license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.
5. Respondent shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months (due by each January 1 and July 1), beginning with whichever date occurs first after this Agreement becomes effective, stating truthfully whether or not it has complied with all terms and conditions of its disciplinary order.
6. Respondent shall not serve as an intern training facility for Missouri interns.
7. Respondent shall make a representative of the pharmacy available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Respondent will be notified and given sufficient time to arrange these meetings.
8. Respondent's failure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary Agreement.

9. The parties to this Agreement understand that the Board of Pharmacy will maintain this Agreement as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

B. Upon the expiration of said discipline, Respondent's license as a pharmacy in Missouri shall be fully restored if all other requirements of law have been satisfied provided, however, that in the event the Board determines that the Respondent has violated any term or condition of this Settlement Agreement, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline Respondent.

C. No order shall be entered by the Board pursuant to the preceding paragraph of this Settlement Agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.

D. If the Board determines that Respondent has violated a term or condition of this Settlement Agreement, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Settlement Agreement in its determination of appropriate legal actions concerning that violation. If any alleged violation of this Settlement Agreement occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this Settlement Agreement has occurred.

E. The terms of this Settlement Agreement are contractual, legally enforceable, binding, and not merely recitals. Except as otherwise contained herein, neither this Settlement Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except

by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

F. Respondent hereby waives and releases the Board, its members and any of its employees, agents, or attorneys, including any former board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs, and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to Section 536.087, RSMo, or any claim arising under 42 U.S.C. §1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this Settlement Agreement in that it survives in perpetuity even in the event that any court of law deems this Settlement Agreement or any portion thereof void or unenforceable.

**RESPONDENT, AS EVIDENCED BY THE INITIALS ON THE APPROPRIATE LINE,**

                     **REQUESTS**

Blk **DOES NOT REQUEST**

**THE ADMINISTRATIVE HEARING COMMISSION TO DETERMINE IF THE FACTS SET FORTH HEREIN ARE GROUNDS FOR DISCIPLINING RESPONDENT'S LICENSE AS A PHARMACY.**

If Respondent has requested review, Respondent and Board jointly request that the Administrative Hearing Commission determine whether the facts set forth herein are grounds for disciplining Respondent's permit and issue findings of fact and conclusions of law stating that the facts agreed to by the parties are grounds for disciplining Respondent's permit. Effective fifteen (15) days from the date the Administrative Hearing Commission determines that the Settlement

Agreement sets forth cause for disciplining Respondent's permit, the agreed upon discipline set forth herein shall go into effect.

If Respondent has not requested review by the Administrative Hearing Commission, the Settlement Agreement goes into effect fifteen (15) days after the document is signed by the Board's Executive Director.

RESPONDENT  
HEART OF AMERICA  
PHARMACY, LLC

By:



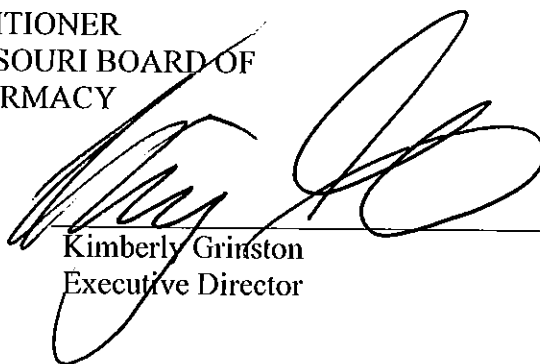
As Authorized Agent for  
HEART OF AMERICA  
PHARMACY, LLC

Printed: Brian Killingsworth

Date: 1-29-18

PETITIONER  
MISSOURI BOARD OF  
PHARMACY

By:

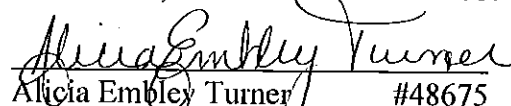


Kimberly Grinston  
Executive Director

Date: 2/5/18

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